



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

December 13, 2001

MEMORANDUM

Subject: Acute Toxicity Review for EPA Reg. No.: 74286-R / Dishwasher Magic
DP Barcode: D277787
Case No: 071137

To: Adam Heyward, PM 34 / Drusilla Copeland
Regulatory Management Branch II
Antimicrobials Division (7510C)

From: Ian Blackwell, Biologist
Efficacy Evaluation Team
Product Science Branch
Antimicrobials Division (7510C)

Through: Karen Hicks, Team Leader
Chemistry and Toxicology Team
Product Science Branch
Antimicrobials Division (7510C)

[Handwritten signature: Karen Hicks]
12/13/01

Michele E. Wingfield, Chief
Product Science Branch
Antimicrobials Division (7510C)

Applicant: Dishwasher Magic LLC

FORMULATION FROM LABEL:

Active Ingredient(s):

Citric Acid

Other Ingredient(s):

% by wt.

25

75

Total: 100%

BACKGROUND: Dishwasher Magic LLC has submitted a set of acute toxicity studies in support of their product, "Dishwasher Magic". Only five acute toxicity/ irritation studies were included in this submission. Waivers were requested for the acute inhalation toxicity and the dermal sensitization studies. The waivers were requested based on the double closure of the ready-to-use container. The other studies were conducted by Product Safety Labs. The MRID Numbers are 4548114-04, 454814-05, 454875-02, and 454875-03. The EPA contractor Oak Ridge National Laboratory did the primary review of these studies.

RECOMMENDATIONS: PSB findings are:

1. The acute oral toxicity, acute dermal toxicity, primary eye irritation and primary skin irritation studies are acceptable.
2. The waivers for the acute inhalation toxicity and the dermal sensitization studies are acceptable.

The acute toxicity profile for EPA File Symbol 74286-R is currently:

acute oral toxicity	IV	acceptable
acute dermal toxicity	III	acceptable
acute inhalation toxicity	IV (Waived)	acceptable
primary eye irritation	IV	acceptable
primary skin irritation	IV	acceptable
dermal sensitization	IV (Waived)	acceptable

LABELING:

In the statements of practical treatment; "IF ON SKIN or CLOTHING" should be listed before "IF IN EYES." All other precautionary statements are acceptable as given.

DATA EVALUATION RECORD

**CITRIC ACID
(DISHWASHER MAGIC)**

**STUDY TYPE: ACUTE ORAL TOXICITY - RAT
[OPPTS 870.1100 [§81-1]; OECD 401]
MRID 45481404**

Prepared for
Antimicrobials Division
Office of Pesticide Programs
U.S. Environmental Protection Agency
1921 Jefferson Davis Highway
Arlington, VA 22202

Prepared by
Toxicology and Hazard Assessment Group
Life Sciences Division
Oak Ridge National Laboratory
Oak Ridge, TN 37831
Action No. K348

Primary Reviewer:
Susan Chang, M.S.

Date:

Signature: _____

Secondary Reviewers:

H. Tim Borges, M.T.(A.S.C.P.), Ph.D., D.A.B.T.

Date:

Signature: _____

Robert H. Ross, M.S., Group Leader

Date:

Signature: _____

Quality Assurance:
Eric Lewis, M.S.

Date:

Signature: _____

Disclaimer

This review may have been altered subsequent to the contractor's signatures above.

EPA Reviewer: Ian Blackwell, M.S.
Antimicrobials Division (9510C)

Signature: _____
Date _____

EPA Work Assignment Manager: B. Akinlosotu, Ph.D.
Antimicrobials Division (9510C)

Signature: _____
Date _____

TXR#:

DATA EVALUATION RECORD

STUDY TYPE: Acute Oral Toxicity - Rat; OPPTS 870.1100 [§81-1]; OECD 401.

PC CODE: 021801

DP BARCODE: D277787
SUBMISSION NO.: S603153

TEST MATERIAL: Dishwasher Magic® (25.1% citric acid, a.i.)

SYNONYMS: Not reported

CITATION: Merkel, D.J. (2001) Acute oral toxicity study in rats - Limit test. Product Safety Labs, 725 Cranbury Road, East Brunswick, NJ 08816. Laboratory study No. 10668, August 8, 2001. MRID 45481404. Unpublished.

SPONSOR: Dishwasher Magic LLC, P.O. Box 61, Wyckoff, NJ 074481

EXECUTIVE SUMMARY: In an acute oral toxicity study (MRID 45481404) five male and five female fasted young adult Sprague-Dawley rats were given a single oral dose of Dishwasher Magic® (25.1% citric acid, a.i.; Batch No. 41201) at doses of 5000 mg/kg body weight (limit test) and observed for 14 days.

Oral LD₅₀ **Males** > 5000 mg/kg bw
 Females > 5000 mg/kg bw
 Combined > 5000 mg/kg bw (limit test)

Dishwasher Magic® is of **LOW Toxicity** based on the LD₅₀ in males or females (EPA Toxicity Category IV).

All rats survived, gained weight, and appeared active and healthy during the study. No gross abnormalities were noted at necropsy.

This acute oral study is classified as acceptable (guideline). This study satisfies the guideline requirements for an acute oral study (OPPTS 870.1100; OECD 401) in the rat.

COMPLIANCE: Signed and dated GLP, Quality Assurance, and Data Confidentiality statements were provided.

I. MATERIALS AND METHODS**A. MATERIALS:**

1. **Test material:** Dishwasher Magic®
Description: Clear liquid
Lot/Batch #: 41201
Composition: 25.1% citric acid, a.i.
CAS # of TGA: 77-92-9

2. **Vehicle and/or positive control:** None

3. **Test animals:**

Species: Rat
Strain: Sprague-Dawley
Age/weight at dosing: Young adult (8-9 weeks); males: 198-214 g, females: 167-172 g
Source: Ace Animals, Inc., Boyertown, PA
Housing: Individually housed in suspended stainless steel caging with mesh floors
Diet: Purina Rodent Chow No. 5012
Water: Filtered tap water, *ad libitum*
Environmental conditions: **Temperature:** 21-24°C
Humidity: not reported
Air changes: not reported
Photoperiod: 12 hrs dark/12 hrs light
Acclimation period: 7 days

B. STUDY DESIGN and METHODS:

1. **In life dates** - Start: June 19, 2001; End: July 3, 2001
2. **Animal assignment and treatment** - Animals were assigned to the test groups noted in Table 1. Five male and five female rats were given a single dose of Dishwasher Magic® by gavage then observed at 1 and 3 hours post dosing and at least once daily for 14 days. They were weighed prior to dosing and on study days 7 and 14. Survivors were sacrificed and a necropsy was performed.

TABLE 1. Doses, mortality/animals treated

Dose (mg/kg bw)	Males	Females	Combined
5000	0/5	0/5	0/10

3. **Statistics** - Calculation of the oral LD₅₀ was not required.

II. RESULTS AND DISCUSSION:

A. **MORTALITY** is given in Table 1. None of the rats died during the study.

The oral LD₅₀ (C.I.) for males is > 5000 mg/kg.

females is > 5000 mg/kg.

combined is > 5000 mg/kg (limit test).

B. **CLINICAL OBSERVATIONS** - All rats appeared active and healthy during the study.

C. **BODY WEIGHT** - All rats had normal body weight gains.

D. **NECROPSY** - No gross abnormalities were noted at necropsy.

E. **REVIEWER'S CONCLUSIONS** - The oral LD₅₀ is > 5000 mg/kg for males, females, and combined. These conclusions are in agreement with the study author.

F. **DEFICIENCIES** - The humidity and air change frequency of the animal room were not reported. These would not affect the study results.

DATA EVALUATION RECORD

CITRIC ACID (DISHWASHER MAGIC)

STUDY TYPE: ACUTE DERMAL TOXICITY - RAT
[OPPTS 870.1200 (§81-2); OECD 402]
MRID 45481405

Prepared for
Antimicrobials Division
Office of Pesticide Programs
U.S. Environmental Protection Agency
1921 Jefferson Davis Highway
Arlington, VA 22202

Prepared by
Toxicology and Hazard Assessment Group
Life Sciences Division
Oak Ridge National Laboratory
Oak Ridge, TN 37831
Action No. K348

Primary Reviewer:
Susan Chang, M.S.

Date:

Signature: _____

Secondary Reviewers:

H. Tim Borges, M.T.(A.S.C.P.), Ph.D., D.A.B.T.

Date:

Signature: _____

Robert H. Ross, M.S., Group Leader

Date:

Signature: _____

Quality Assurance:

Eric Lewis, M.S.

Date:

Signature: _____

Disclaimer

This review may have been altered subsequent to the contractor's signatures above.

Oak Ridge National Laboratory managed and operated by UT-Battelle, LLC, for the U.S. Department of Energy under Contract No. DE-AC05-00OR22725.

DRAFT Label
(SIDE PANEL)

DIRECTIONS FOR USE

It is a violation of Federal Law to use this product in a manner inconsistent with it's labeling. Read the entire label before using this product.

TO CLEAN:

1. Remove cap. DO NOT REMOVE RED PLUG.
2. **MAKE SURE YOUR AUTOMATIC DISHWASHER IS EMPTY.**
3. Place the bottle upside down in the bottom rack inside the silverware basket.

A rectangular box containing the text "Picture of silverware basket in dishwasher."
4. Do not use soap.
5. Close dishwasher door, then set to normal wash cycle. Start dishwasher.
6. After full cycle is complete, and dishwasher is off, remove bottle and discard.

NOTE: FOR HEAVILY STAINED DISHWASHERS, A SECOND APPLICATION OF DISHWASHER MAGIC MAY BE NECESSARY.

When the waters inside the dishwasher reaches 125°F (in wash cycle), the red plug in the bottle will dissolve and the solution inside will dispense.

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage and disposal.

PESTICIDE STORAGE AND DISPOSAL

Storage: Store unopened package in a cool, dry place in areas inaccessible to small children.

Container Disposal: Do not reuse empty container. Wrap and put in trash.

EPA Registration No. 74286-
EPA Establishment No. _____

(FRONT PANEL)

Dishwasher Magic®

Picture of dishwashing machine
with door open.

Removes Lime Scale, Calcium, Soap Scum, Grease & Iron

KILLS 99.9% of BACTERIA INSIDE DISHWASHER*

Active Ingredient: Citric Acid	25.0%
Other Ingredient(s):	75.0%

Net Contents: 12 FL. OZ. (375 m) Read side panel carefully.

KEEP OUT OF REACH OF CHILDREN

CAUTION

PRECAUTIONARY STATEMENTS

Harmful if absorbed through the skin. Causes moderate eye irritation. Avoid contact with skin, eyes, or clothing. Wash thoroughly with soap and water after handling. In case of contact, immediately flush eyes or skin with plenty of water. Get medical attention if irritation persists.

STATEMENT OF PRACTICAL TREATMENT

IF IN EYES:

- Hold eye open and rinse slowly and gently with water for 15-20 minutes.
- Remove contact lenses, if present, after the first five minutes, then continue rinsing eye.
- Call a poison control center or doctor for treatment advice.

IF ON SKIN OR CLOTHING:

- Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes.
- Call a poison control center or doctor for treatment advice.

Have the product container or label with you when calling a poison control center or doctor, or going for treatment.

*KILLS 99.9% of *Salmonella* and *E. coli*.

Manufactured for:
Dishwasher Magic LLC
Wyckoff, NJ 07481

EPA Reviewer: Ian Blackwell, M.S.
Antimicrobials Division (9510C)

Signature: _____
Date _____

EPA Work Assignment Manager: B. Akinlosotu, Ph.D.
Antimicrobials Division (9510C)

Signature: _____
Date _____

TXR#:

DATA EVALUATION RECORD

STUDY TYPE: Acute Dermal Toxicity - Rat; OPPTS 870.1200 [§81-2]; OECD 402.

PC CODE: 021801

DP BARCODE: D277787
SUBMISSION NO.: S603153

TEST MATERIAL: Dishwasher Magic® (25.1% citric acid, a.i.)

SYNONYMS: Not reported

CITATION: Merkel, D.J. (2001) Acute dermal toxicity study in rats - Limit test.
Product Safety Labs, 725 Cranbury Road, East Brunswick, NJ 08816.
Laboratory study No. 10669, August 8, 2001. MRID 45481405.
Unpublished.

SPONSOR: Dishwasher Magic LLC, P.O. Box 61, Wyckoff, NJ 074481

EXECUTIVE SUMMARY: In an acute dermal toxicity study (MRID 45481405), five male and five female Sprague-Dawley rats were dermally exposed to Dishwasher Magic® (25.1% citric acid, a.i.; Batch No. 41201) for 24 hours to approximately 10% of the body surface area at dose of 2000 mg/kg body weight (limit test). The animals then were observed for 14 days.

Dermal LD50	Males > 2000 mg/kg bw
Females	> 2000 mg/kg bw
Combined	> 2000 mg/kg bw (limit test)

Dishwasher Magic® is of **LOW Toxicity** based on the LD₅₀ in males and females (EPA Toxicity Category III).

All rats survived, gained weight, and appeared active and healthy during the study. No gross abnormalities were noted at necropsy.

This acute dermal study is classified as acceptable (guideline). This study satisfies the guideline requirement for an acute dermal toxicity study (OPPTS 870.1200; OECD 402) in the rat.

COMPLIANCE: Signed and dated GLP, Quality Assurance, and Data Confidentiality statements were provided.

I. MATERIALS AND METHODS

A. MATERIALS:

1. Test material: Dishwasher Magic®

Description: Clear liquid
Lot/Batch #: 41201
Purity: 25.1% citric acid, a.i.
CAS # of 77-92-9
TGAI:
Structure: NA

2. Vehicle and/or positive control: None

3. Test animals:

Species: Rat
Strain: Sprague-Dawley
Age/weight at dosing: Young adult (9-11 weeks); males: 264-286 g, females: 167-195 g
Source: Ace Animals, Inc., Boyertown, PA
Housing: Individually housed in suspended stainless steel caging with mesh floors
Diet: Purina Rodent Chow No. 5012
Water: Filtered tap water, *ad libitum*
Environmental conditions: **Temperature:** 21-24°C
Humidity: Not reported
Air changes: Not reported
Photoperiod: 12 hrs dark/12 hrs light
Acclimation period: 7 or 28 days

B. STUDY DESIGN and METHODS:

1. In life dates – Start: June 19, 2001; End: July 3, 2001

2. Animal assignment and treatment – Animals were assigned to the test groups noted in Table 1. Animals were given a single dose 2000 mg/kg bw (limit test) of Dishwasher Magic® dermally applied to a clipped area (approximately 2 inches x 3 inches) on the dorsal trunk (approximately 10% of the body surface). The application site was covered with a gauze pad and wrapped with Durapore tape. The covering was removed 24 hours later and the site wiped with water and a towel to remove any residual test material. The rats were observed 1 and 5 hours after treatment and at least daily thereafter for 14 days. They were weighed prior to test material application, and on study days 7 and 14. Survivors were sacrificed and a necropsy was performed.

TABLE 1. Doses, mortality/animals treated

Dose (mg/kg bw)	Males	Females	Combined
2000	0/5	0/5	0/10

3. **Statistics** – Calculation of the dermal LD₅₀ was not required.

II. RESULTS AND DISCUSSION:

A. **MORTALITY** is given in Table 1. None of the rats died during the study.

The dermal LD₅₀ (C.I.) for males is > 2000 mg/kg bw.
females is > 2000 mg/kg bw.
combined is > 2000 mg/kg bw (limit test).

B. **CLINICAL OBSERVATIONS** – All rats appeared normal during the study.

C. **BODY WEIGHT** – All rats had normal body weight gains.

D. **NECROPSY** – All rats had no abnormalities at necropsy.

E. **REVIEWER'S CONCLUSIONS** – The dermal LD₅₀ was > 2000 mg/kg bw for males, females, and combined. These conclusions are in agreement with the study author.

F. **DEFICIENCIES** – The humidity and air change frequency of the animal room were not reported. These would not affect the study results.

DATA EVALUATION RECORD

CITRIC ACID (DISHWASHER MAGIC)

STUDY TYPE: PRIMARY EYE IRRITATION - RABBIT
[OPPTS 870.2400 [§81-4]; OECD 405]
MRID 45487502

Prepared for
Antimicrobials Division
Office of Pesticide Programs
U.S. Environmental Protection Agency
1921 Jefferson Davis Highway
Arlington, VA 22202

Prepared by
Toxicology and Hazard Assessment Group
Life Sciences Division
Oak Ridge National Laboratory
Oak Ridge, TN 37831
Action No. K348

Primary Reviewer:

Susan Chang, M.S.

Signature: _____

Date: _____

Secondary Reviewers:

H. Tim Borges, M.T.(A.S.C.P.), Ph.D., D.A.B.T.

Signature: _____

Date: _____

Robert H. Ross, M.S., Group Leader

Signature: _____

Date: _____

Quality Assurance:

Lee Ann Wilson, M.A.

Signature: _____

Date: _____

Disclaimer

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Oak Ridge National Laboratory managed and operated by UT-Battelle, LLC., for the U.S. Department of Energy under Contract No. DE-AC05-00OR22725.

EPA Reviewer: Ian Blackwell, M.S.

Antimicrobials Division (9510C)

EPA Work Assignment Manager: B. Akinlosotu, Ph.D.

Antimicrobials Division (9510C)

Signature: _____**Date:** _____**Signature:** _____**Date:** _____**TXR#:**

DATA EVALUATION RECORD

STUDY TYPE: Primary Eye Irritation - Rabbit; OPPTS 870.2400 [§81-4]; OECD 405.**PC CODE:** 021801**DP BARCODE:** D277787**SUBMISSION NO.:** S603153**TEST MATERIAL:** Dishwasher Magic® (25.1% citric acid, a.i.)**SYNONYMS:** Not reported**CITATION:** Merkel, D.J. (2001) Primary eye irritation study in rabbits. Product Safety Labs, 725 Cranbury Road, East Brunswick, NJ 08816. Laboratory study No. 10670, August 8, 2001. MRID 45487502. Unpublished.**SPONSOR:** Dishwasher Magic LLC, P.O. Box 61, Wyckoff, NJ 074481

EXECUTIVE SUMMARY: In a primary eye irritation study (MRID 45487502), 0.1 mL of Dishwasher Magic® (25.1% citric acid, a.i.; Batch No. 41201) was instilled into the right conjunctival sac of one female and two male young adult New Zealand white rabbits. The contralateral eye of all rabbits served as control. Animals then were observed for 3 days. The eyes were scored for ocular irritation according to the Draize method 1, 24, 48, and 72 hours after instillation and the irritation classified according to the method of Kay and Calandra.

No corneal opacity, iritis, or positive conjunctival irritation (score ≥ 2) were found on any rabbit.

In this study, Dishwasher Magic® was minimally irritating to the eye based on the highest maximum mean total score of 6.0 recorded one hour after test material instillation (EPA Toxicity Category IV).

This study is classified as acceptable (guideline). This study satisfies the guideline requirement for a primary eye irritation study (OPPTS 870.2400; OECD 405) in the rabbit.

COMPLIANCE: Signed and dated GLP, Quality Assurance, and Data Confidentiality statements were provided.

I. MATERIALS AND METHODS

A. MATERIALS:

- | | |
|--------------------------|-------------------------|
| 1. Test material: | Dishwasher Magic® |
| Description: | Clear liquid |
| Lot/Batch #: | 41201 |
| Purity: | 25.1% citric acid, a.i. |
| CAS # of TGA: | 77-92-9 |
-

2. Vehicle and/or positive control: None

3. Test animals:

Species:	Rabbit
Strain:	New Zealand white
Age/weight at dosing:	Young adult; weight of males and female not reported
Source:	Davidson's Mill Farm, South Brunswick, NJ
Housing:	Individually housed in suspended stainless steel caging with mesh floors
Diet:	Pelleted Purina Rabbit Chow No. 5326
Water:	Filtered tap water, <i>ad libitum</i>
Environmental conditions:	Temperature: 18-22°C Humidity: not reported Air changes: not reported Photoperiod: 12 hrs dark/12 hrs light
Acclimation period:	12 days

B. STUDY DESIGN and METHODS:

1. **In life dates** - Start: June 25, 2001; End: June 28, 2001
2. **Animal assignment and treatment** - The test material (0.1 mL) was instilled into the right conjunctival sac of one female and two male rabbits and the eye lids held together for approximately 1 second. The contralateral eye of all rabbits served as control. The animals were scored for ocular irritation 1, 24, 48, and 72 hours after instillation according to the Draize method and the degree of irritation classified according to the method of Kay and Calandra.

II. RESULTS AND DISCUSSION

- A. No corneal opacity, iritis, or positive conjunctival irritation (score ≥ 2) were found on any rabbit. Conjunctival irritation (score 1) was noted on 3/3 rabbits one hour after test material instillation with resolution by 72 hours. The highest maximum mean total score was 6.0, recorded one hour after test material instillation.

- B. **REVIEWER'S CONCLUSIONS** - The test material was minimally irritating. These conclusions are in agreement with the study author.

- C. **DEFICIENCIES** - The humidity and air change frequency of the animal room were not reported. These would not affect the study results.

DATA EVALUATION RECORD

**CITRIC ACID
(DISHWASHER MAGIC)**

**STUDY TYPE: PRIMARY DERMAL IRRITATION - RABBIT
[OPPTS 870.2500 [§81-5]; OECD 404]
MRID 45487503**

Prepared for
Antimicrobials Division
Office of Pesticide Programs
U.S. Environmental Protection Agency
1921 Jefferson Davis Highway
Arlington, VA 22202

Prepared by
Toxicology and Hazard Assessment Group
Life Sciences Division
Oak Ridge National Laboratory
Oak Ridge, TN 37831
Action No. K348

Primary Reviewer:

Susan Chang, M.S.

Signature: _____

Date: _____

Secondary Reviewers:

H. Tim Borges, M.T.(A.S.C.P.), Ph.D., D.A.B.T.

Signature: _____

Date: _____

Robert H. Ross, M.S., Group Leader

Signature: _____

Date: _____

Quality Assurance:

Eric Lewis, M.S.

Signature: _____

Date: _____

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EPA Reviewer: Ian Blackwell, M.S.
Antimicrobials Division (9510C)

EPA Work Assignment Manager: B. Akinlosotu, Ph.D.
Antimicrobials Division (9510C)

Signature: _____

Date _____

Signature: _____

Date _____

TXR#:

DATA EVALUATION RECORD

STUDY TYPE: Primary Dermal Irritation - Rabbit; OPPTS 870.2500 [§81-5]: OECD 404.

PC CODE: 021801

DP BARCODE: D277787

SUBMISSION NO.: S603153

TEST MATERIAL: Dishwasher Magic® (25.1% citric acid, a.i.)

SYNONYMS: Not reported

CITATION: Merkel, D.J. (2001) Primary skin irritation in rabbits. Product Safety Labs, 725 Cranbury Road, East Brunswick, NJ 08816. Laboratory study No. 10671, August 8, 2001. MRID 45487503. Unpublished.

SPONSOR: Dishwasher Magic LLC, P.O. Box 61, Wyckoff, NJ 074481

EXECUTIVE SUMMARY: In a primary dermal irritation study (MRID 45487503), one male and two female New Zealand white rabbits were dermally exposed to 0.5 mL of Dishwasher Magic® (25.1% citric acid, a.i.; Batch No. 41201) for four hours to an area of approximately 6 cm² body surface. The animals then were observed for 3 days. Irritation was scored by the method of Draize.

Very slight erythema (barely perceptible) was noted on 3/3 rabbits one through 24 hours after patch removal with resolution by 48 hours. The primary dermal irritation index was 0.5.

In this study, Dishwasher Magic® was slightly irritating (EPA Toxicity Category IV).

This study is classified as acceptable (guideline). This study satisfies the guideline requirement for a primary dermal irritation study (OPPTS 870.2500; OECD 404) in the rabbit.

COMPLIANCE: Signed and dated GLP, Quality Assurance, and Data Confidentiality statements were provided.

I. MATERIALS AND METHODS

A. MATERIALS:

1. **Test material:** Dishwasher Magic®
Description: Cear liquid
Lot/Batch #: 41201
Purity: 25.1% citric acid, a.i.
CAS # of TGAI: 77-92-9

2. **Vehicle and/or positive control:** None

3. **Test animals:**

Species:	Rabbit
Strain:	New Zealand white
Age/weight at treatment:	Young adult; weight of males and female not reported
Source:	Davidson's Mill Farm, South Brunswick, NJ
Housing:	Individually housed in suspended stainless steel caging with mesh floors
Diet:	Pelleted Purina Rabbit Chow No. 5326
Water:	Filtered tap water, <i>ad libitum</i>
Environmental conditions:	Temperature: 17-22°C Humidity: not reported Air changes: not reported Photoperiod: 12 hrs dark/12 hrs light
Acclimation period:	18 days

B. STUDY DESIGN and METHODS:

1. **In life dates** - Start: June 19, 2001; End: June 22, 2001
2. **Animal assignment and treatment** - One male and two female animals were given a single 0.5 mL dose of Dishwasher Magic® applied to a 6 cm² clipped intact site on the dorsal trunk. The application sites were covered with a gauze pad and wrapped with semi-occlusive tape. The dressings were left in place for 4 hours, after which they were removed and the residual test material removed with water and a towel. The sites were scored for erythema and edema according to the Draize method 1, 24, 48, and 72 hours after patch removal.

II. RESULTS AND DISCUSSION:

- A. Very slight erythema (barely perceptible) was noted on 3/3 rabbits one through 24 hours after patch removal with resolution by 48 hours. The primary dermal irritation index was 0.5.

- B. REVIEWER'S CONCLUSIONS** - The test material was slightly irritating. These conclusions are in agreement with the study author.
- C. DEFICIENCIES** - The humidity and air change frequency of the animal room were not reported. These would not affect the study results.

EPA Reviewer: Ian Blackwell, Ph.D.
Antimicrobials Division (9510C)
EPA Work Assignment Manager: B. Akinlosotu, Ph.D.
Antimicrobials Division (9510C)

Signature: _____
Date _____
Signature: _____
Date _____

TXR#:

DATA EVALUATION RECORD

STUDY TYPE: Primary Dermal Irritation - Rabbit; OPPTS 870.2500 [§81-5]: OECD 404.

PC CODE: 021801

DP BARCODE: D277787
SUBMISSION NO.: S603153

TEST MATERIAL: Dishwasher Magic® (25.1% citric acid, a.i.)

SYNONYMS: Not reported

CITATION: Merkel, D.J. (2001) Primary skin irritation in rabbits. Product Safety Labs, 725 Cranbury Road, East Brunswick, NJ 08816. Laboratory study No. 10671, August 8, 2001. MRID 45487503. Unpublished.

SPONSOR: Dishwasher Magic LLC, P.O. Box 61, Wyckoff, NJ 074481

EXECUTIVE SUMMARY: In a primary dermal irritation study (MRID 45487503), one male and two female New Zealand white rabbits were dermally exposed to 0.5 mL of Dishwasher Magic® (25.1% citric acid, a.i.; Batch No. 41201) for four hours to an area of approximately 6 cm² body surface. The animals then were observed for 3 days. Irritation was scored by the method of Draize.

Very slight erythema (barely perceptible) was noted on 3/3 rabbits one through 24 hours after patch removal with resolution by 48 hours. The primary dermal irritation index was 0.5.

In this study, Dishwasher Magic® was slightly irritating (EPA Toxicity Category IV).

This study is classified as acceptable (guideline). This study satisfies the guideline requirement for a primary dermal irritation study (OPPTS 870.2500; OECD 404) in the rabbit.

COMPLIANCE: Signed and dated GLP, Quality Assurance, and Data Confidentiality statements were provided.

I. MATERIALS AND METHODS**A. MATERIALS:****1. Test material:** Dishwasher Magic®

Description: Cear liquid
Lot/Batch #: 41201
Purity: 25.1% citric acid, a.i.
CAS # of TGAI: 77-92-9

2. Vehicle and/or positive control: None**3. Test animals:**

Species: Rabbit
Strain: New Zealand white
Age/weight at treatment: Young adult; weight of males and female not reported
Source: Davidson's Mill Farm, South Brunswick, NJ
Housing: Individually housed in suspended stainless steel caging with mesh floors
Diet: Pelleted Purina Rabbit Chow No. 5326
Water: Filtered tap water, *ad libitum*
Environmental conditions: **Temperature:** 17-22°C
Humidity: not reported
Air changes: not reported
Photoperiod: 12 hrs dark/12 hrs light
Acclimation period: 18 days

B. STUDY DESIGN and METHODS:**1. In life dates** - Start: June 19, 2001; End: June 22, 2001

2. Animal assignment and treatment - One male and two female animals were given a single 0.5 mL dose of Dishwasher Magic® applied to a 6 cm² clipped intact site on the dorsal trunk. The application sites were covered with a gauze pad and wrapped with semi-occlusive tape. The dressings were left in place for 4 hours, after which they were removed and the residual test material removed with water and a towel. The sites were scored for erythema and edema according to the Draize method 1, 24, 48, and 72 hours after patch removal.

II. RESULTS AND DISCUSSION:

A. Very slight erythema (barely perceptible) was noted on 3/3 rabbits one through 24 hours after patch removal with resolution by 48 hours. The primary dermal irritation index was 0.5.

B. REVIEWER'S CONCLUSIONS - The test material was slightly irritating. These conclusions are in agreement with the study author.

- C. **DEFICIENCIES** - The humidity and air change frequency of the animal room were not reported. These would not affect the study results.

DATA EVALUATION RECORD

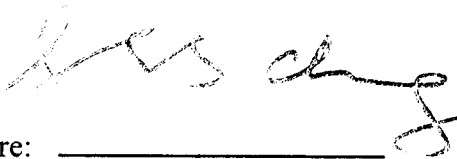
**CITRIC ACID
(DISHWASHER MAGIC)**

STUDY TYPE: PRIMARY DERMAL IRRITATION - RABBIT
[OPPTS 870.2500 [§81-5]; OECD 404]
MRID 45487503

Prepared for
Antimicrobials Division
Office of Pesticide Programs
U.S. Environmental Protection Agency
1921 Jefferson Davis Highway
Arlington, VA 22202

Prepared by
Toxicology and Hazard Assessment Group
Life Sciences Division
Oak Ridge National Laboratory
Oak Ridge, TN 37831
Action No. K348

Primary Reviewer:
Susan Chang, M.S.

Signature: 
Date: OCT 29 2001

Secondary Reviewers:
H. Tim Borges, M.T.(A.S.C.P.), Ph.D., D.A.B.T.

Signature: HT Borges
Date: OCT 29 2001

Robert H. Ross, M.S., Group Leader

Signature: Robert H. Ross
Date: OCT 29 2001

Quality Assurance:
Eric Lewis, M.S.

Signature: Eric B. Lewis
Date: OCT 29 2001

Disclaimer

This review may have been altered subsequent to the contractor's signatures above.

EPA Reviewer: Ian Blackwell, Ph.D.
Antimicrobials Division (9510C)
EPA Work Assignment Manager: B. Akinlosotu, Ph.D.
Antimicrobials Division (9510C)

Signature: _____
Date _____
Signature: _____
Date _____

TXR#:

DATA EVALUATION RECORD

STUDY TYPE: Primary Dermal Irritation - Rabbit; OPPTS 870.2500 [§81-5]: OECD 404.

PC CODE: 021801

DP BARCODE: D277787
SUBMISSION NO.: S603153

TEST MATERIAL: Dishwasher Magic® (25.1% citric acid, a.i.)

SYNONYMS: Not reported

CITATION: Merkel, D.J. (2001) Primary skin irritation in rabbits. Product Safety Labs, 725 Cranbury Road, East Brunswick, NJ 08816. Laboratory study No. 10671, August 8, 2001. MRID 45487503. Unpublished.

SPONSOR: Dishwasher Magic LLC, P.O. Box 61, Wyckoff, NJ 074481

EXECUTIVE SUMMARY: In a primary dermal irritation study (MRID 45487503), one male and two female New Zealand white rabbits were dermally exposed to 0.5 mL of Dishwasher Magic® (25.1% citric acid, a.i.; Batch No. 41201) for four hours to an area of approximately 6 cm² body surface. The animals then were observed for 3 days. Irritation was scored by the method of Draize.

Very slight erythema (barely perceptible) was noted on 3/3 rabbits one through 24 hours after patch removal with resolution by 48 hours. The primary dermal irritation index was 0.5.

In this study, Dishwasher Magic® was slightly irritating (EPA Toxicity Category IV).

This study is classified as acceptable (guideline). This study satisfies the guideline requirement for a primary dermal irritation study (OPPTS 870.2500; OECD 404) in the rabbit.

COMPLIANCE: Signed and dated GLP, Quality Assurance, and Data Confidentiality statements were provided.

I. MATERIALS AND METHODS

A. MATERIALS:

1. **Test material:** Dishwasher Magic®

Description: Clear liquid
Lot/Batch #: 41201
Purity: 25.1% citric acid, a.i.
CAS # of TGAI: 77-92-9

2. **Vehicle and/or positive control:** None

3. **Test animals:**

Species: Rabbit
Strain: New Zealand white
Age/weight at treatment: Young adult; weight of males and female not reported
Source: Davidson's Mill Farm, South Brunswick, NJ
Housing: Individually housed in suspended stainless steel caging with mesh floors
Diet: Pelleted Purina Rabbit Chow No. 5326
Water: Filtered tap water, *ad libitum*
Environmental conditions: Temperature: 17-22°C
Humidity: not reported
Air changes: not reported
Photoperiod: 12 hrs dark/12 hrs light
Acclimation period: 18 days

B. STUDY DESIGN and METHODS:

1. **In life dates** - Start: June 19, 2001; End: June 22, 2001

2. **Animal assignment and treatment** - One male and two female animals were given a single 0.5 mL dose of Dishwasher Magic® applied to a 6 cm² clipped intact site on the dorsal trunk. The application sites were covered with a gauze pad and wrapped with semi-occlusive tape. The dressings were left in place for 4 hours, after which they were removed and the residual test material removed with water and a towel. The sites were scored for erythema and edema according to the Draize method 1, 24, 48, and 72 hours after patch removal.

II. RESULTS AND DISCUSSION:

- A. Very slight erythema (barely perceptible) was noted on 3/3 rabbits one through 24 hours after patch removal with resolution by 48 hours. The primary dermal irritation index was 0.5.

- B. **REVIEWER'S CONCLUSIONS** - The test material was slightly irritating. These conclusions are in agreement with the study author.

- C. **DEFICIENCIES** - The humidity and air change frequency of the animal room were not reported. These would not affect the study results.

EPA Reviewer: Ian Blackwell, Ph.D.
Antimicrobials Division (9510C)
EPA Work Assignment Manager: B. Akinlosotu, Ph.D.
Antimicrobials Division (9510C)

Signature: _____
Date: _____
Signature: _____
Date: _____

TXR#:

DATA EVALUATION RECORD

STUDY TYPE: Primary Eye Irritation - Rabbit; OPPTS 870.2400 [§81-4]; OECD 405.

PC CODE: 021801

DP BARCODE: D277787
SUBMISSION NO.: S603153

TEST MATERIAL: Dishwasher Magic® (25.1% citric acid, a.i.)

SYNONYMS: Not reported

CITATION: Merkel, D.J. (2001) Primary eye irritation study in rabbits. Product Safety Labs, 725 Cranbury Road, East Brunswick, NJ 08816. Laboratory study No. 10670, August 8, 2001. MRID 45487502. Unpublished.

SPONSOR: Dishwasher Magic LLC, P.O. Box 61, Wyckoff, NJ 074481

EXECUTIVE SUMMARY: In a primary eye irritation study (MRID 45487502), 0.1 mL of Dishwasher Magic® (25.1% citric acid, a.i.; Batch No. 41201) was instilled into the right conjunctival sac of one female and two male young adult New Zealand white rabbits. The contralateral eye of all rabbits served as control. Animals then were observed for 3 days. The eyes were scored for ocular irritation according to the Draize method 1, 24, 48, and 72 hours after instillation and the irritation classified according to the method of Kay and Calandra.

No corneal opacity, iritis, or positive conjunctival irritation (score ≥ 2) were found on any rabbit.

In this study, Dishwasher Magic® was minimally irritating to the eye based on the highest maximum mean total score of 6.0 recorded one hour after test material instillation (EPA Toxicity Category IV).

This study is classified as acceptable (guideline). This study satisfies the guideline requirement for a primary eye irritation study (OPPTS 870.2400; OECD 405) in the rabbit.

COMPLIANCE: Signed and dated GLP, Quality Assurance, and Data Confidentiality statements were provided.

I. MATERIALS AND METHODS

A. MATERIALS:

1. **Test material:** Dishwasher Magic®
Description: Clear liquid
Lot/Batch #: 41201
Purity: 25.1% citric acid, a.i.
CAS # of TGAI: 77-92-9
-

2. **Vehicle and/or positive control:** None

3. **Test animals:**

Species:	Rabbit
Strain:	New Zealand white
Age/weight at dosing:	Young adult; weight of males and female not reported
Source:	Davidson's Mill Farm, South Brunswick, NJ
Housing:	Individually housed in suspended stainless steel caging with mesh floors
Diet:	Pelleted Purina Rabbit Chow No. 5326
Water:	Filtered tap water, <i>ad libitum</i>
Environmental conditions:	Temperature: 18-22°C Humidity: not reported Air changes: not reported Photoperiod: 12 hrs dark/12 hrs light
Acclimation period:	12 days

B. STUDY DESIGN and METHODS:

1. **In life dates** - Start: June 25, 2001; End: June 28, 2001
2. **Animal assignment and treatment** - The test material (0.1 mL) was instilled into the right conjunctival sac of one female and two male rabbits and the eye lids held together for approximately 1 second. The contralateral eye of all rabbits served as control. The animals were scored for ocular irritation 1, 24, 48, and 72 hours after instillation according to the Draize method and the degree of irritation classified according to the method of Kay and Calandra.

II. RESULTS AND DISCUSSION

- A. No corneal opacity, iritis, or positive conjunctival irritation (score ≥ 2) were found on any rabbit. Conjunctival irritation (score 1) was noted on 3/3 rabbits one hour after test material instillation with resolution by 72 hours. The highest maximum mean total score was 6.0, recorded one hour after test material instillation.
- B. **REVIEWER'S CONCLUSIONS** - The test material was minimally irritating. These conclusions are in agreement with the study author.

C. **DEFICIENCIES** - The humidity and air change frequency of the animal room were not reported. These would not affect the study results.

DATA EVALUATION RECORD

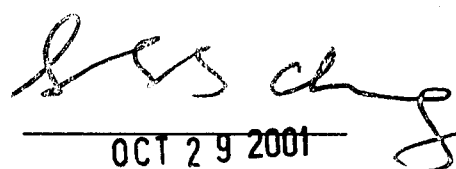
CITRIC ACID (DISHWASHER MAGIC)

STUDY TYPE: PRIMARY EYE IRRITATION - RABBIT
[OPPTS 870.2400 [§81-4]; OECD 405]
MRID 45487502

Prepared for
Antimicrobials Division
Office of Pesticide Programs
U.S. Environmental Protection Agency
1921 Jefferson Davis Highway
Arlington, VA 22202

Prepared by
Toxicology and Hazard Assessment Group
Life Sciences Division
Oak Ridge National Laboratory
Oak Ridge, TN 37831
Action No. K348

Primary Reviewer:
Susan Chang, M.S.

Signature: 
Date: OCT 29 2001

Secondary Reviewers:
H. Tim Borges, M.T.(A.S.C.P.), Ph.D., D.A.B.T.

Signature: H.T. Borges
Date: OCT 29 2001

Robert H. Ross, M.S., Group Leader

Signature: Robert H. Ross
Date: OCT 29 2001

Quality Assurance:
Lee Ann Wilson, M.A.

Signature: L.A. Wilson
Date: OCT 29 2001

Disclaimer

This review may have been altered subsequent to the contractor's signatures above.

EPA Reviewer: Ian Blackwell, Ph.D.
Antimicrobials Division (9510C)
EPA Work Assignment Manager: B. Akinlosotu, Ph.D.
Antimicrobials Division (9510C)

Signature: _____
Date: _____
Signature: _____
Date: _____

TXR#:

DATA EVALUATION RECORD

STUDY TYPE: Primary Eye Irritation - Rabbit; OPPTS 870.2400 [§81-4]; OECD 405.

PC CODE: 021801

DP BARCODE: D277787
SUBMISSION NO.: S603153

TEST MATERIAL: Dishwasher Magic® (25.1% citric acid, a.i.)

SYNONYMS: Not reported

CITATION: Merkel, D.J. (2001) Primary eye irritation study in rabbits. Product Safety Labs, 725 Cranbury Road, East Brunswick, NJ 08816. Laboratory study No. 10670, August 8, 2001. MRID 45487502. Unpublished.

SPONSOR: Dishwasher Magic LLC, P.O. Box 61, Wyckoff, NJ 074481

EXECUTIVE SUMMARY: In a primary eye irritation study (MRID 45487502), 0.1 mL of Dishwasher Magic® (25.1% citric acid, a.i.; Batch No. 41201) was instilled into the right conjunctival sac of one female and two male young adult New Zealand white rabbits. The contralateral eye of all rabbits served as control. Animals then were observed for 3 days. The eyes were scored for ocular irritation according to the Draize method 1, 24, 48, and 72 hours after instillation and the irritation classified according to the method of Kay and Calandra.

No corneal opacity, iritis, or positive conjunctival irritation (score ≥ 2) were found on any rabbit.

In this study, Dishwasher Magic® was minimally irritating to the eye based on the highest maximum mean total score of 6.0 recorded one hour after test material instillation (EPA Toxicity Category IV).

This study is classified as acceptable (guideline). This study satisfies the guideline requirement for a primary eye irritation study (OPPTS 870.2400; OECD 405) in the rabbit.

COMPLIANCE: Signed and dated GLP, Quality Assurance, and Data Confidentiality statements were provided.

I. MATERIALS AND METHODS

A. MATERIALS:

1. **Test material:** Dishwasher Magic®
Description: Clear liquid
Lot/Batch #: 41201
Purity: 25.1% citric acid, a.i.
CAS # of TGAI: 77-92-9
-

2. **Vehicle and/or positive control:** None

3. **Test animals:**

Species:	Rabbit
Strain:	New Zealand white
Age/weight at dosing:	Young adult; weight of males and female not reported
Source:	Davidson's Mill Farm, South Brunswick, NJ
Housing:	Individually housed in suspended stainless steel caging with mesh floors
Diet:	Pelleted Purina Rabbit Chow No. 5326
Water:	Filtered tap water, <i>ad libitum</i>
Environmental conditions:	Temperature: 18-22°C
	Humidity: not reported
	Air changes: not reported
	Photoperiod: 12 hrs dark/12 hrs light
Acclimation period:	12 days

B. STUDY DESIGN and METHODS:

1. **In life dates** - Start: June 25, 2001; End: June 28, 2001
2. **Animal assignment and treatment** - The test material (0.1 mL) was instilled into the right conjunctival sac of one female and two male rabbits and the eye lids held together for approximately 1 second. The contralateral eye of all rabbits served as control. The animals were scored for ocular irritation 1, 24, 48, and 72 hours after instillation according to the Draize method and the degree of irritation classified according to the method of Kay and Calandra.

II. RESULTS AND DISCUSSION

- A. No corneal opacity, iritis, or positive conjunctival irritation (score ≥ 2) were found on any rabbit. Conjunctival irritation (score 1) was noted on 3/3 rabbits one hour after test material instillation with resolution by 72 hours. The highest maximum mean total score was 6.0, recorded one hour after test material instillation.
- B. **REVIEWER'S CONCLUSIONS** - The test material was minimally irritating. These conclusions are in agreement with the study author.

- C. **DEFICIENCIES** - The humidity and air change frequency of the animal room were not reported. These would not affect the study results.

EPA Reviewer: Ian Blackwell, Ph.D.
Antimicrobials Division (9510C)
EPA Work Assignment Manager: B. Akinlosotu, Ph.D.
Antimicrobials Division (9510C)

Signature: _____
Date _____
Signature: _____
Date _____

TXR#:

DATA EVALUATION RECORD

STUDY TYPE: Acute Dermal Toxicity - Rat; OPPTS 870.1200 [§81-2]; OECD 402.

PC CODE: 021801

DP BARCODE: D277787
SUBMISSION NO.: S603153

TEST MATERIAL: Dishwasher Magic® (25.1% citric acid, a.i.)

SYNONYMS: Not reported

CITATION: Merkel, D.J. (2001) Acute dermal toxicity study in rats - Limit test. Product Safety Labs, 725 Cranbury Road, East Brunswick, NJ 08816. Laboratory study No. 10669, August 8, 2001. MRID 45481405. Unpublished.

SPONSOR: Dishwasher Magic LLC, P.O. Box 61, Wyckoff, NJ 074481

EXECUTIVE SUMMARY: In an acute dermal toxicity study (MRID 45481405), five male and five female Sprague-Dawley rats were dermally exposed to Dishwasher Magic® (25.1% citric acid, a.i.; Batch No. 41201) for 24 hours to approximately 10% of the body surface area at dose of 2000 mg/kg body weight (limit test). The animals then were observed for 14 days.

Dermal LD50 Males > 2000 mg/kg bw
Females > 2000 mg/kg bw
Combined > 2000 mg/kg bw (limit test)

Dishwasher Magic® is of **LOW Toxicity** based on the LD₅₀ in males and females (EPA Toxicity Category III).

All rats survived, gained weight, and appeared active and healthy during the study. No gross abnormalities were noted at necropsy.

This acute dermal study is classified as acceptable (guideline). This study satisfies the guideline requirement for an acute dermal toxicity study (OPPTS 870.1200; OECD 402) in the rat.

COMPLIANCE: Signed and dated GLP, Quality Assurance, and Data Confidentiality statements were provided.

I. MATERIALS AND METHODS**A. MATERIALS:****1. Test material:** Dishwasher Magic®

Description: Clear liquid
Lot/Batch #: 41201
Purity: 25.1% citric acid, a.i.
CAS # of 77-92-9
TGAI:
Structure: NA

2. Vehicle and/or positive control: None**3. Test animals:**

Species: Rat
Strain: Sprague-Dawley
Age/weight at dosing: Young adult (9-11 weeks); males: 264-286 g, females: 167-195 g
Source: Ace Animals, Inc., Boyertown, PA
Housing: Individually housed in suspended stainless steel caging with mesh floors
Diet: Purina Rodent Chow No. 5012
Water: Filtered tap water, *ad libitum*
Environmental conditions: Temperature: 21-24°C
Humidity: Not reported
Air changes: Not reported
Photoperiod: 12 hrs dark/12 hrs light
Acclimation period: 7 or 28 days

B. STUDY DESIGN and METHODS:**1. In life dates** – Start: June 19, 2001; End: July 3, 2001

2. Animal assignment and treatment – Animals were assigned to the test groups noted in Table 1. Animals were given a single dose 2000 mg/kg bw (limit test) of Dishwasher Magic® dermally applied to a clipped area (approximately 2 inches x 3 inches) on the dorsal trunk (approximately 10% of the body surface). The application site was covered with a gauze pad and wrapped with Durapore tape. The covering was removed 24 hours later and the site wiped with water and a towel to remove any residual test material. The rats were observed 1 and 5 hours after treatment and at least daily thereafter for 14 days. They were weighed prior to test material application, and on study days 7 and 14. Survivors were sacrificed and a necropsy was performed.

TABLE 1. Doses, mortality/animals treated

Dose (mg/kg bw)	Males	Females	Combined
2000	0/5	0/5	0/10

3. **Statistics** – Calculation of the dermal LD₅₀ was not required.

II. RESULTS AND DISCUSSION:

A. **MORTALITY** is given in Table 1. None of the rats died during the study.

The dermal LD₅₀ (C.I.) for males is > 2000 mg/kg bw.
females is > 2000 mg/kg bw.
combined is > 2000 mg/kg bw (limit test).

B. **CLINICAL OBSERVATIONS** – All rats appeared normal during the study.

C. **BODY WEIGHT** – All rats had normal body weight gains.

D. **NECROPSY** – All rats had no abnormalities at necropsy.

E. **REVIEWER'S CONCLUSIONS** – The dermal LD₅₀ was > 2000 mg/kg bw for males, females, and combined. These conclusions are in agreement with the study author.

F. **DEFICIENCIES** – The humidity and air change frequency of the animal room were not reported. These would not affect the study results.

DATA EVALUATION RECORD

CITRIC ACID (DISHWASHER MAGIC)

STUDY TYPE: ACUTE DERMAL TOXICITY - RAT
[OPPTS 870.1200 (§81-2); OECD 402]
MRID 45481405

Prepared for
Antimicrobials Division
Office of Pesticide Programs
U.S. Environmental Protection Agency
1921 Jefferson Davis Highway
Arlington, VA 22202

Prepared by
Toxicology and Hazard Assessment Group
Life Sciences Division
Oak Ridge National Laboratory
Oak Ridge, TN 37831
Action No. K348

Primary Reviewer:
Susan Chang, M.S.

Signature: 
Date: OCT 29 2001

Secondary Reviewers:
H. Tim Borges, M.T.(A.S.C.P.), Ph.D., D.A.B.T.

Signature: HT Borges
Date: OCT 29 2001

Robert H. Ross, M.S., Group Leader

Signature: Robert H. Ross
Date: OCT 29 2001

Quality Assurance:
Eric Lewis, M.S.

Signature: Eric B. Lewis
Date: OCT 29 2001

Disclaimer

This review may have been altered subsequent to the contractor's signatures above.

EPA Reviewer: Ian Blackwell, Ph.D.
Antimicrobials Division (9510C)
EPA Work Assignment Manager: B. Akinlosotu, Ph.D.
Antimicrobials Division (9510C)

Signature: _____
Date _____
Signature: _____
Date _____

TXR#:

DATA EVALUATION RECORD

STUDY TYPE: Acute Dermal Toxicity - Rat; OPPTS 870.1200 [§81-2]; OECD 402.

PC CODE: 021801

DP BARCODE: D277787
SUBMISSION NO.: S603153

TEST MATERIAL: Dishwasher Magic® (25.1% citric acid, a.i.)

SYNONYMS: Not reported

CITATION: Merkel, D.J. (2001) Acute dermal toxicity study in rats - Limit test. Product Safety Labs, 725 Cranbury Road, East Brunswick, NJ 08816. Laboratory study No. 10669, August 8, 2001. MRID 45481405. Unpublished.

SPONSOR: Dishwasher Magic LLC, P.O. Box 61, Wyckoff, NJ 074481

EXECUTIVE SUMMARY: In an acute dermal toxicity study (MRID 45481405), five male and five female Sprague-Dawley rats were dermally exposed to Dishwasher Magic® (25.1% citric acid, a.i.; Batch No. 41201) for 24 hours to approximately 10% of the body surface area at dose of 2000 mg/kg body weight (limit test). The animals then were observed for 14 days.

Dermal LD50 Males > 2000 mg/kg bw
Females > 2000 mg/kg bw
Combined > 2000 mg/kg bw (limit test)

Dishwasher Magic® is of **LOW Toxicity** based on the LD₅₀ in males and females (EPA Toxicity Category III).

All rats survived, gained weight, and appeared active and healthy during the study. No gross abnormalities were noted at necropsy.

This acute dermal study is classified as acceptable (guideline). This study satisfies the guideline requirement for an acute dermal toxicity study (OPPTS 870.1200; OECD 402) in the rat.

COMPLIANCE: Signed and dated GLP, Quality Assurance, and Data Confidentiality statements were provided.

I. MATERIALS AND METHODS**A. MATERIALS:****1. Test material:** Dishwasher Magic®

Description: Clear liquid
Lot/Batch #: 41201
Purity: 25.1% citric acid, a.i.
CAS # of 77-92-9
TGAI:
Structure: NA

2. Vehicle and/or positive control: None**3. Test animals:**

Species: Rat
Strain: Sprague-Dawley
Age/weight at dosing: Young adult (9-11 weeks); males: 264-286 g, females: 167-195 g
Source: Ace Animals, Inc., Boyertown, PA
Housing: Individually housed in suspended stainless steel caging with mesh floors
Diet: Purina Rodent Chow No. 5012
Water: Filtered tap water, *ad libitum*
Environmental conditions: Temperature: 21-24°C
Humidity: Not reported
Air changes: Not reported
Photoperiod: 12 hrs dark/12 hrs light
Acclimation period: 7 or 28 days

B. STUDY DESIGN and METHODS:**1. In life dates** – Start: June 19, 2001; End: July 3, 2001

2. Animal assignment and treatment – Animals were assigned to the test groups noted in Table 1. Animals were given a single dose 2000 mg/kg bw (limit test) of Dishwasher Magic® dermally applied to a clipped area (approximately 2 inches x 3 inches) on the dorsal trunk (approximately 10% of the body surface). The application site was covered with a gauze pad and wrapped with Durapore tape. The covering was removed 24 hours later and the site wiped with water and a towel to remove any residual test material. The rats were observed 1 and 5 hours after treatment and at least daily thereafter for 14 days. They were weighed prior to test material application, and on study days 7 and 14. Survivors were sacrificed and a necropsy was performed.

TABLE 1. Doses, mortality/animals treated

Dose (mg/kg bw)	Males	Females	Combined
2000	0/5	0/5	0/10

3. **Statistics** – Calculation of the dermal LD₅₀ was not required.

II. RESULTS AND DISCUSSION:

A. **MORTALITY** is given in Table 1. None of the rats died during the study.

The dermal LD₅₀ (C.I.) for males is > 2000 mg/kg bw.
females is > 2000 mg/kg bw.
combined is > 2000 mg/kg bw (limit test).

B. **CLINICAL OBSERVATIONS** – All rats appeared normal during the study.

C. **BODY WEIGHT** – All rats had normal body weight gains.

D. **NECROPSY** – All rats had no abnormalities at necropsy.

E. **REVIEWER'S CONCLUSIONS** – The dermal LD₅₀ was > 2000 mg/kg bw for males, females, and combined. These conclusions are in agreement with the study author.

F. **DEFICIENCIES** – The humidity and air change frequency of the animal room were not reported. These would not affect the study results.

EPA Reviewer: Ian Blackwell, Ph.D.
Antimicrobials Division (9510C)
EPA Work Assignment Manager: B. Akinlosotu, Ph.D.
Antimicrobials Division (9510C)

Signature: _____
Date _____
Signature: _____
Date _____

TXR#:

DATA EVALUATION RECORD

STUDY TYPE: Acute Oral Toxicity - Rat; OPPTS 870.1100 [§81-1]; OECD 401.

PC CODE: 021801

DP BARCODE: D277787
SUBMISSION NO.: S603153

TEST MATERIAL: Dishwasher Magic® (25.1% citric acid, a.i.)

SYNONYMS: Not reported

CITATION: Merkel, D.J. (2001) Acute oral toxicity study in rats - Limit test. Product Safety Labs, 725 Cranbury Road, East Brunswick, NJ 08816. Laboratory study No. 10668, August 8, 2001. MRID 45481404. Unpublished.

SPONSOR: Dishwasher Magic LLC, P.O. Box 61, Wyckoff, NJ 074481

EXECUTIVE SUMMARY: In an acute oral toxicity study (MRID 45481404) five male and five female fasted young adult Sprague-Dawley rats were given a single oral dose of Dishwasher Magic® (25.1% citric acid, a.i.; Batch No. 41201) at doses of 5000 mg/kg body weight (limit test) and observed for 14 days.

Oral LD₅₀ Males > 5000 mg/kg bw
 Females > 5000 mg/kg bw
 Combined > 5000 mg/kg bw (limit test)

Dishwasher Magic® is of **LOW Toxicity** based on the LD₅₀ in males or females (EPA Toxicity Category IV).

All rats survived, gained weight, and appeared active and healthy during the study. No gross abnormalities were noted at necropsy.

This acute oral study is classified as acceptable (guideline). This study satisfies the guideline requirements for an acute oral study (OPPTS 870.1100; OECD 401) in the rat.

COMPLIANCE: Signed and dated GLP, Quality Assurance, and Data Confidentiality statements were provided.

I. MATERIALS AND METHODS**A. MATERIALS:****1. Test material:** Dishwasher Magic®

Description: Clear liquid
Lot/Batch #: 41201
Composition: 25.1% citric acid, a.i.
CAS # of TGA: 77-92-9

2. Vehicle and/or positive control: None**3. Test animals:**

Species: Rat
Strain: Sprague-Dawley
Age/weight at dosing: Young adult (8-9 weeks); males: 198-214 g, females: 167-172 g
Source: Ace Animals, Inc., Boyertown, PA
Housing: Individually housed in suspended stainless steel caging with mesh floors
Diet: Purina Rodent Chow No. 5012
Water: Filtered tap water, *ad libitum*
Environmental conditions: **Temperature:** 21-24°C
Humidity: not reported
Air changes: not reported
Photoperiod: 12 hrs dark/12 hrs light
Acclimation period: 7 days

B. STUDY DESIGN and METHODS:**1. In life dates** - Start: June 19, 2001; End: July 3, 2001**2. Animal assignment and treatment** - Animals were assigned to the test groups noted in Table 1. Five male and five female rats were given a single dose of Dishwasher Magic® by gavage then observed at 1 and 3 hours post dosing and at least once daily for 14 days. They were weighed prior to dosing and on study days 7 and 14. Survivors were sacrificed and a necropsy was performed.

TABLE 1. Doses, mortality/animals treated

Dose (mg/kg bw)	Males	Females	Combined
5000	0/5	0/5	0/10

3. Statistics - Calculation of the oral LD₅₀ was not required.**II. RESULTS AND DISCUSSION:**

A. **MORTALITY** is given in Table 1. None of the rats died during the study.

The oral LD₅₀ (C.I.) for males is > 5000 mg/kg.
females is > 5000 mg/kg.
combined is > 5000 mg/kg (limit test).

B. **CLINICAL OBSERVATIONS** - All rats appeared active and healthy during the study.

C. **BODY WEIGHT** - All rats had normal body weight gains.

D. **NECROPSY** - No gross abnormalities were noted at necropsy.

E. **REVIEWER'S CONCLUSIONS** - The oral LD₅₀ is > 5000 mg/kg for males, females, and combined. These conclusions are in agreement with the study author.

F. **DEFICIENCIES** - The humidity and air change frequency of the animal room were not reported. These would not affect the study results.

DATA EVALUATION RECORD

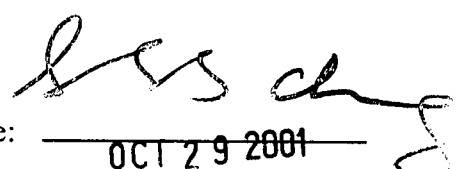
CITRIC ACID (DISHWASHER MAGIC)

STUDY TYPE: ACUTE ORAL TOXICITY - RAT
[OPPTS 870.1100 [§81-1]; OECD 401]
MRID 45481404

Prepared for
Antimicrobials Division
Office of Pesticide Programs
U.S. Environmental Protection Agency
1921 Jefferson Davis Highway
Arlington, VA 22202

Prepared by
Toxicology and Hazard Assessment Group
Life Sciences Division
Oak Ridge National Laboratory
Oak Ridge, TN 37831
Action No. K348

Primary Reviewer:
Susan Chang, M.S.

Signature: 
Date: OCT 29 2001

Secondary Reviewers:
H. Tim Borges, M.T.(A.S.C.P.), Ph.D., D.A.B.T.

Signature: H.T. Borges
Date: OCT 29 2001

Robert H. Ross, M.S., Group Leader

Signature: Robert H. Ross
Date: OCT 29 2001

Quality Assurance:
Eric Lewis, M.S.

Signature: Eric B. Lewis
Date: OCT 29 2001

Disclaimer

This review may have been altered subsequent to the contractor's signatures above.

EPA Reviewer: Ian Blackwell, Ph.D.
Antimicrobials Division (9510C)
EPA Work Assignment Manager: B. Akinlosotu, Ph.D.
Antimicrobials Division (9510C)

Signature: _____
Date _____
Signature: _____
Date _____

TXR#:

DATA EVALUATION RECORD

STUDY TYPE: Acute Oral Toxicity - Rat; OPPTS 870.1100 [§81-1]; OECD 401.

PC CODE: 021801

DP BARCODE: D277787
SUBMISSION NO.: S603153

TEST MATERIAL: Dishwasher Magic® (25.1% citric acid, a.i.)

SYNONYMS: Not reported

CITATION: Merkel, D.J. (2001) Acute oral toxicity study in rats - Limit test. Product Safety Labs, 725 Cranbury Road, East Brunswick, NJ 08816. Laboratory study No. 10668, August 8, 2001. MRID 45481404. Unpublished.

SPONSOR: Dishwasher Magic LLC, P.O. Box 61, Wyckoff, NJ 074481

EXECUTIVE SUMMARY: In an acute oral toxicity study (MRID 45481404) five male and five female fasted young adult Sprague-Dawley rats were given a single oral dose of Dishwasher Magic® (25.1% citric acid, a.i.; Batch No. 41201) at doses of 5000 mg/kg body weight (limit test) and observed for 14 days.

Oral LD₅₀ Males > 5000 mg/kg bw
 Females > 5000 mg/kg bw
 Combined > 5000 mg/kg bw (limit test)

Dishwasher Magic® is of **LOW Toxicity** based on the LD₅₀ in males or females (EPA Toxicity Category IV).

All rats survived, gained weight, and appeared active and healthy during the study. No gross abnormalities were noted at necropsy.

This acute oral study is classified as acceptable (guideline). This study satisfies the guideline requirements for an acute oral study (OPPTS 870.1100; OECD 401) in the rat.

COMPLIANCE: Signed and dated GLP, Quality Assurance, and Data Confidentiality statements were provided.

I. MATERIALS AND METHODS**A. MATERIALS:****1. Test material:** Dishwasher Magic®

Description: Clear liquid
 Lot/Batch #: 41201
 Composition: 25.1% citric acid, a.i.
 CAS # of TGAI: 77-92-9

2. Vehicle and/or positive control: None**3. Test animals:**

Species: Rat
 Strain: Sprague-Dawley
 Age/weight at dosing: Young adult (8-9 weeks); males: 198-214 g, females: 167-172 g
 Source: Ace Animals, Inc., Boyertown, PA
 Housing: Individually housed in suspended stainless steel caging with mesh floors
 Diet: Purina Rodent Chow No. 5012
 Water: Filtered tap water, *ad libitum*
 Environmental conditions: Temperature: 21-24°C
 Humidity: not reported
 Air changes: not reported
 Photoperiod: 12 hrs dark/12 hrs light
 Acclimation period: 7 days

B. STUDY DESIGN and METHODS:

- 1. In life dates** - Start: June 19, 2001; End: July 3, 2001
- 2. Animal assignment and treatment** - Animals were assigned to the test groups noted in Table 1. Five male and five female rats were given a single dose of Dishwasher Magic® by gavage then observed at 1 and 3 hours post dosing and at least once daily for 14 days. They were weighed prior to dosing and on study days 7 and 14. Survivors were sacrificed and a necropsy was performed.

TABLE 1. Doses, mortality/animals treated

Dose (mg/kg bw)	Males	Females	Combined
5000	0/5	0/5	0/10

- 3. Statistics** - Calculation of the oral LD₅₀ was not required.

II. RESULTS AND DISCUSSION:

DATA EVALUATION RECORD

CITRIC ACID (DISHWASHER MAGIC)

STUDY TYPE: ACUTE INHALATION TOXICITY - RAT
[OPPTS 870.1300 [§81-3]; OECD 403]
SKIN SENSITIZATION - GUINEA PIG
[OPPTS 870.2600 [§81-6]; OECD 406]
MRID Not assigned

Prepared for
Antimicrobials Division
Office of Pesticide Programs
U.S. Environmental Protection Agency
1921 Jefferson Davis Highway
Arlington, VA 22202

Prepared by
Toxicology and Hazard Assessment Group
Life Sciences Division
Oak Ridge National Laboratory
Oak Ridge, TN 37831
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Antimicrobials Division (9510C)

Signature: _____
Date _____
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Date _____

TXR#:

DATA EVALUATION RECORD

STUDY TYPE: Acute Inhalation Toxicity - Rat; OPPTS 870.1300 [§81-3]; OECD 403.
Skin Sensitization - Guinea Pig; OPPTS 870.2600 [§81-6]; OECD 406.

PC CODE: 021801

DP BARCODE: D277787
SUBMISSION NO.: S603153

TEST MATERIAL: Dishwasher Magic® (25.1% citric acid, a.i.)

SYNONYMS: Not reported

CITATION: Wagner, J.M. (2001) Acute inhalation toxicity and skin sensitization: Request for data waivers. Wagner Regulatory Associates, Inc., P.O. Box 7954, Wilmington, DE 19803. Report No. WRA-01-004, August 10, 2001. MRID not assigned. Unpublished.

SPONSOR: Dishwasher Magic LLC, P.O. Box 61, Wyckoff, NJ 074481

REVIEWER'S CONCLUSIONS: Dishwasher Magic® is intended to clean the inside of automatic dishwashers. The ready-to-use package has a double closure system consisting of an outer cap which is to be removed by the user and an inner plug which will be melted when the inside of the dishwasher reaches approximately 125°F. The user is not exposed at anytime to the contents of the product under normal and customary conditions of use.

The registrant is requesting a wavier for the requirements for acute inhalation toxicity data and skin sensitization testing.

DATA EVALUATION RECORD

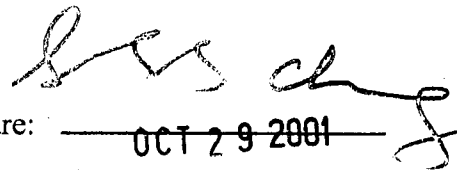
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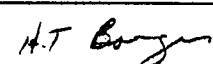
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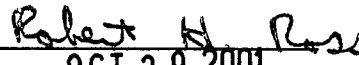
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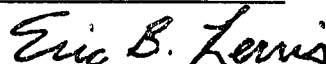
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Skin Sensitization - Guinea Pig; OPPTS 870.2600 [§81-6]; OECD 406.

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